REMARKS

Telephone Interview of May 20, 2004

Applicant's Agent thanks the Examiner for the courtesies extended during the telephone interview held May 20, 2004.

During the interview the Examiner noted that the Declaration was complete, rather than defective, and stated that the draft revised Abstract should be acceptable. Concerns regarding the §112 rejections of the pending claims were also discussed.

Oath/Declaration

The Office Action states that the oath or declaration is defective because it does not state that the person making the oath or declaration believes that named inventor to be the original and first inventor of the subject matter claimed and for which a patent is sought and that a new oath or declaration compliant with 37 CFR 1.67(a) is required.

Applicant notes that the required statement is present on page 1 of the two page Combined Declaration and Power of Attorney, filed with the application, in the Section entitled Inventorship Identification. As the required statement is present in the Combined Declaration and Power of Attorney submitted with the application, Applicant believes that no new oath or declaration is required at this time.

Amendments to the Specification

The replacement page 1 and replacement Abstract (p. 13) correct the pagination problem noted in the Office Action. The replacement Abstract also meets the required length limitation.

Further, Applicant herein amends Table 2 to correct a typographic error in describing Key 2 in the table. Support for this amendment is found in the Abstract as filed and on p. 5, final line.

Applicant asserts that no new matter is introduced in these amendments and respectfully requests entry of the proposed amendments.

Amendments to the Claims

Claim 1 is amended to correct an antecedent basis problem and to clarify the language of the final transmitting step. Support for this amendment is found in claims 1 and 6 as filed and in the specification at p. 6, 2nd paragraph to p. 7, line 8. Dependent claims 2, 3 and 5 are amended to be consistent with claim 1. Support for these amendments is found in claims 1, 2, 3 and 5 as filed.

Claim 6 is amended to correct an antecedent basis problem and to clarify the language. Claim 7, depending from claim 6, is amended to be consistent with independent claim 6. Support for these amendments is found in claims 6 and 7 as filed.

Claim 8 is amended to clarify the language and to incorporate the limitations of claim 9, which is canceled. Support for these amendments is found in claims 8 and 9 as filed, and in the specification at p. 4, last paragraph, lines 1-4 bridging to p. 5, lines 1-2.

Claim 10 is amended to correct an antecedent basis problem. Support for this amendment is found in claim 10 as filed, and in the specification at p. 5, last line to p. 6, first line.

Claim 13 is amended to correct an antecedent basis problem. Support for this amendment is found in claims 10 and 13 as filed. Claim 16 is amended to be consistent with claim 13, from which it depends. Support for this amendment is found in the specification at p.6, 3rd paragraph, lines 4-6. Claim 17 is amended to depend from claim 16 and to clarify the language. Support for this amendment is found in the specification at p. 6, 3rd paragraph, line 3 to 4th paragraph, line5.

Claim 18 is amended to correct antecedent basis problems. Support for this amendment is found in the claim as filed and in the specification at p. 3, final paragraph to p. 7, 1st paragraph.

Claim 19 is amended to correct antecedent basis problems. Support for this amendment is found in the claim as filed and in the specification at p. 5, final line bridging to p. 6, line 1.

Applicant asserts that no new matter is introduced in these amendments and respectfully requests entry of the proposed claim amendments.

35 USC §112 Rejections, 2nd Paragraph

The Office Action rejects claims 1-19 under 35 USC §112, 2nd paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action rejects claim 1 under 35 USC §112, 2nd paragraph for reciting the limitation "the results", for which there is insufficient antecedent basis in the claim. The Office Action also rejects claim 1 under 35 USC §112, 2nd paragraph for reciting the limitation "devoid of accessible patient identification", stating that it is unclear as to who can and can't access the information that is in the request.

Claim 1 is amended to provide antecedent basis for "the results". Claim 1 is also amended to indicate that the second medical test request is devoid of *publicly* accessible patient identification.

The Office Action also rejects claim 1 under 35 USC §112, 2nd paragraph because the transmitting step in claim 1 seems to include many steps. The "many steps" referred to in the Office Action are meant to define functions that the secure data provider performs. Claim 1 is amended to clarify the functions of the secure data provider to which the specimen and the first medical test request are transmitted in the transmitting step.

As the stated reasons for the 35 USC §112, 2nd paragraph rejections are addressed with these amendments, applicant requests withdrawal of the rejections of claim 1 under 35 USC §112, 2nd paragraph.

The Office Action rejects claim 6 under 35 USC §112, 2nd paragraph for reciting the limitation "the results", for which there is insufficient antecedent basis in the claim. Claim 6 is herein amended to provide antecedent basis for "results" in the preamble. As the stated reason for the 35 USC §112, 2nd paragraph rejection is addressed with this amendment, applicant requests withdrawal of the rejection of claim 6 under 35 USC §112, 2nd paragraph.

The Office Action rejects claim 8 under 35 USC §112, 2nd paragraph for reciting an unclear list of included items on a data card. Claim 8 is amended to clarify the list of items and to incorporate the limitations of claim 9, which is canceled. As the stated reason for the 35 USC §112, 2nd paragraph rejection is addressed with this amendment, applicant requests withdrawal of the rejection of claim 8 under 35 USC §112, 2nd paragraph.

The Office Action rejects claim 10 under 35 USC §112, 2nd paragraph for reciting the limitation "the test type", for which there is insufficient antecedent basis in the claim. Claim 10 is herein amended to refer to "a medical test type", correcting the antecedent basis problem. As the stated reason for the 35 USC §112, 2nd paragraph rejection is addressed with this amendment, applicant requests withdrawal of the rejection of claim 10 under 35 USC §112, 2nd paragraph.

The Office Action rejects claim 13 under 35 USC §112, 2nd paragraph for reciting the limitation "the results", for which there is insufficient antecedent basis in the claim. Claim 13 is herein amended to correct the lack of antecedent basis problem. As the stated reason for the 35 USC §112, 2nd paragraph rejection is addressed with this amendment, applicant requests withdrawal of the rejection of claim 13 under 35 USC §112, 2nd paragraph.

The Office Action rejects claim 17 under 35 USC §112, 2nd paragraph for reciting the additional limitation "comprising a patient identification code" in addition to the limitation "information identifying the patient" recited in claim 13, without clearly differentiating the two as separate limitations. Claim 17 is amended to recite "a unique patient identification number".

Applicant asserts that when read in conjunction with the description of the invention at p. 6, third through fifth paragraphs, amended claim 17 is introducing an additional limitation on the test results card of claim 13. Independent claim 13 is directed to a test results card including *encrypted* information identifying the patient, while claim 17 is directed to the test results card of claim 13 which further includes a unique patient identification number, i.e, a patient identifier which is not encrypted. The test results card of claim 17 permits identification of the patient to be made by a different person or persons than those who could identify the patient from the test results card of claim 13. As discussed in the specification at p. 6, third through fifth paragraphs, the test results card of claim 13 permits only those with access to the proper encryption key to decrypt the information identifying the patient, while the test results card of claim 17 permits those with access to the proper encryption key to decrypt the information identifying the patient but also permits those with information correlating patients with their unique patient identification numbers to identify the patient. Applicant therefore requests reconsideration and withdrawal of the rejection of claim 17 under 35 USC §112, 2nd paragraph.

The Office Action rejects claim 18 under 35 USC §112, 2nd paragraph for reciting the limitation "the encrypted form", for which there is insufficient antecedent basis in the claim. Claim 18 is herein amended to correct the lack of antecedent basis problem. As the stated reason for the 35 USC §112, 2nd paragraph rejection is addressed with this amendment, applicant requests withdrawal of the rejection of claim 18 under 35 USC §112, 2nd paragraph.

The Office Action rejects claim 19 under 35 USC §112, 2nd paragraph for reciting the limitation "the test type", for which there is insufficient antecedent basis in the claim. Claim 19 is herein amended to refer to "a medical test type", correcting the antecedent basis problem. As the stated reason for the 35 USC §112, 2nd paragraph rejection is addressed with this amendment, applicant requests withdrawal of the rejection of claim 19 under 35 USC §112, 2nd paragraph.

The Office Action stated that claims 18 and 19 would be allowable if rewritten or amended to overcome the rejections under 35 USC §112, 2nd paragraph. Claims 18 and 19 are amended herein, as discussed above, to overcome the 35 USC §112, 2nd paragraph rejections. Applicant's Agent therefore believes at least claims 18-19 are in condition for allowance and such favorable action is respectfully requested.

35 USC §102 Rejections

The Office Action rejects Claims 1, 2, 5 and 6 as being anticipated under 35 USC §102(b)

by Keene, US 5,325,294.

The Office Action states that with respect to Claims 1 and 2, the claims are anticipated by Keene because "Keene discloses a method of insuring a patient's privacy from medical tests, by providing the patient with a card containing a unique ID number (col 2, lines 6-10), taking a specimen from the patient (col 3, lines 54-57), requesting a test with user ID on data card (col 3 lines 54-56) and a second test request is generated devoid of publicly accessible patient identification (col 3, lines 57-61) and reports results that can only be read with the data card (col 2 lines 58-64)". Further, the Office Action states with respect to Claim 5 that "Keene discloses that the patient must also provide a PIN (column 2, lines 61-64)".

Applicant asserts that the Office Action has failed to establish a *prima facie* case that Keene anticipates claims 1, 2 and 5. For a claim to be anticipated under 35 U.S.C. §102, a single reference must teach every element of the claim. (*Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379.). Moreover, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." (*Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.* 730 F.2d 1452. 221 USPQ 481, 485 (Fed. Cir 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542. 220 USPQ 193 (Fed. Cir. 1983)).

The method of amended claim 1 comprises providing a patient with a medical data card containing a unique patient identification number; taking a specimen from the patient for conducting a medical test; generating a first medical test request containing the unique patient identification number using the patient's medical data card, and transmitting the specimen and the first medical test request to a secure data provider. The secure data provider is one that generates a second medical test request devoid of publicly accessible patient identification information using the first medical test request, transmits the specimen and the second medical test request to a laboratory, receives the test results from the laboratory, and reports the test results on a test results card that can only be read in conjunction with the patient's medical data card. Claims 2 and 5 depend from claim 1.

Contrary to the statements in the Office Action, Keene does not disclose every element of claims 1, 2 and 5. In particular, Keene does not disclose transmitting a patient specimen and a first medical test request to any other party, and certainly not to the recited *secure data provider* that is defined as an entity performing multiple functions in securing the privacy of the patient's results from the medical test. Keene merely discloses referral of the member of a computer database

system to a testing facility (col 2, lines 3-6; col 3, lines 54-55). In the Office Action, this referral to a testing facility appears to have been erroneously equated with the step of "generating a first medical test request containing the unique patient identification number using the patient's medical data card". Applicant notes that Keene does not provide any indication that this request for a medical test is the first of two requests, nor that it contains the unique patient identification number from the patient's medical data card. In Keene, the member databank ID card is used to verify that the person presenting themselves at the testing facility is identical to the member identified on the card. The testing facility obtains a serum specimen after the member's identity is verified, the test is presumably performed by the testing facility since there is no indication otherwise, and the test results are reported to the patient by the testing facility. Thus, Keene fails to disclose the step in claim 1 of transmitting the specimen and the first medical test request to a secure data provider and also does not disclose a secure data provider that performs the functions of generating a second medical test request devoid of publicly accessible patient identification information using the first medical test request, transmitting the specimen and the second medical test request to the laboratory, receiving the results from the medical test from the laboratory, and reporting the results on a test results card that can only be read in conjunction with the patient's medical data card.

Claims 2 and 5 depend from claim 1 and therefore incorporate each limitation of claim 1. Since Keene fails to disclose the transmitting step of claim 1, claims 2 and 5 are also not anticipated by Keene.

As Keene does not anticipate claims 1, 2 and 5, Applicant requests withdrawal of the 35 USC §102(b) rejection of claims 1, 2 and 5 over Keene.

The Office Action states that with respect to Claim 6, the claim is anticipated by Keene because "Keene discloses a method of insuring a patient's privacy from medical tests, by providing the patient with a card containing a unique ID number (col 2, lines 6-10), taking a specimen from the patient (col 3, lines 54-57), requesting a test with user ID on data card (col 3 lines 54-56) and a second test request is generated devoid of publicly accessible patient identification (col 3, lines 57-61) and reports results that can only be read with the data card (col 2 lines 58-64)".

Applicant asserts that the Office Action fails to establish a *prima facie* case that Keene anticipates claim 6. As noted above, for a claim to be anticipated under 35 U.S.C. §102, a single reference must teach every element of the claim. (*Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379.). Moreover, "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim."

(*Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.* 730 F.2d 1452. 221 USPQ 481, 485 (Fed. Cir 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542. 220 USPQ 193 (Fed. Cir. 1983)).

The method of amended claim 6 comprises issuing the patient a medical data card containing a unique patient identification number; receiving from the medical provider a first medical test request generated using the patient's medical data card and a patient specimen for use in conducting the medical test; generating a second medical test request using the first medical test request, the second medical test request being devoid of publicly accessible information about the identity of the patient; forwarding the second medical test request and the specimen to a laboratory for conducting the medical test; receiving the results of the medical test from the laboratory; and providing the results to the medical provider in a form that can only be read in conjunction with the patient's medical data card.

Contrary to the statements in the Office Action, Keene does not disclose every element of claim 6. Several elements of claim 6 are not disclosed in Keene. For example, there is no disclosure in Keene of providing the results of the medical test, in *any form*, to the medical provider, as recited in the final step of claim 6. In contrast, in Keene the testing facility informs the member directly of the results (col 3 lines 61-63) and the results may also be deposited to a databank if the member consents (col 3 lines 65-66).

Also, Keene does not disclose a step of receiving from the medical provider a first medical test request generated using the patient's medical data card and a patient specimen for use in conducting the medical test, as recited in the method of amended claim 6. The Office Action alleges that Keene discloses "requesting a test with user ID on data card", referencing col 3 lines 54-56. The relevant part of col 3 lines 54-56 states "A member is referred to an agreed-upon testing facility where the member's identity will first be verified, using a databank ID card." Thus, the Office Action appears to equate referral to the testing facility in Keene's disclosure with the step in claim 6 of "receiving from the medical provider a first medical test request generated using the patient's medical data card and a patient specimen for use in conducting the medical test". However, Applicant notes that there is no disclosure in Keene in the referenced lines, or elsewhere, that the testing facility to which the member is referred has received any medical test request *from a medical provider* as recited in claim 6, and certainly not a first medical test request generated using the patient's medical data card. In Keene, the role of the member databank ID card is simply to verify the person presenting themselves at the testing facility as the member identified on the

card; Keene does not disclose using the member databank ID card to generate a first medical test request. Moreover, in Keene the medical provider is not providing the patient specimen with that first medical test request. Instead, the testing facility obtains a serum sample directly from the patient after the patient's (member's) identity is verified.

Additionally, Keene does not disclose generating a first medical test request containing the unique patient identification number using the patient's medical data card. Applicant disagrees with the assertion in the Office Action that this step is disclosed at col. 3 lines 57-61 of Keene. The contents of this portion of Keene are as follows "...prior to obtaining a serum specimen. Results are reported according to account number; names are held in a separate non-accessible databank. Medical testing is performed by pre-existing facilities according to approved standards. Responsibility for informing a patient...". These lines contain no reference, either explicitly or implicitly, to generating a second medical test request using the first medical test request, with the second medical test request being devoid of publicly accessible information about the identity of the patient. If referral of the member to the testing facility is equated as a first medical test request, Applicant sees no disclosure elsewhere in Keene of any second medical test request. Moreover, there is no medical test *request* in Keene that is disclosed as being devoid of publicly accessible information about the identity of the patient as recited in claim 6. Keene does disclose that test *results* are devoid of publicly accessible information about the identity of the patient, but does not disclose that any medical test *request* is devoid of publicly accessible identity information.

Further, Keene does not disclose forwarding the second medical test request and the patient specimen to a *laboratory* for conducting the medical test as is required in the method of claim 6. Keene discloses that the member goes to the testing facility, the member has a serum sample taken by the testing facility, testing is performed by "pre-existing facilities according to approved standards". In Keene, there is no disclosure, explicit or implicit, of forwarding the second medical test request and the patient specimen from the testing facility to a laboratory.

Hence, Keene cannot anticipate claim 6 as Keene does not disclose at least four elements of the claim, as discussed above. Applicant therefore requests withdrawal of the 35 USC §102(b) rejection of claim 6 over Keene.

The Office Action rejects claims 8 and 9 under 35 USC §102(a) as being anticipated by Challener et al., US 6,081,793, noting that Challener et al. disclose a card "with stores a unique ID, a private key and a public key (col 3, lines 9-14).

Claim 8 is amended to include the limitations of claim 9 and claim 9 is canceled.

Applicant asserts that the Office Action has failed to establish a *prima facie* case that Challener et al. anticipate amended claim 8. For a claim to be anticipated under 35 U.S.C. §102, a single reference must teach every element of the claim. (*Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379.).

The card of Challener et al. does not possess every element of the claimed card of amended claim 8. The Office Action states that the card disclosed by Challener et al. has a unique ID, a private key and a public key; however, Challener et al. do not disclose a card with a data storage element adapted for storing data for at least one medical test, including for each medical test: a medical test type, a unique identification code for performing the medical test on the patient, and the results of the medical test as does the card claimed in claim 8. Thus, Challener et al. do not anticipate claim 8 as Challener et al. fail to disclose all elements of the claim.

Applicant therefore requests withdrawal of the 35 USC §102(a) rejection of claim 8 over Challener et al.

35 USC §103 Rejections

The Office Action rejects claims 3, 4, 7 and 10-17 under 35 USC §103(a) as being unpatentable over Keene, taking official notice that smart cards are used to store a variety of information.

In particular, with respect to claim 3, the Office Action takes official notice that smart cards are used to store patient medical information and that it would have been "obvious for one of ordinary skill in the art to implement Keene's method on such a card so as to eliminate the need for the patient to carry multiple cards". Applicant requests that the Patent Office cite an authority, pursuant to MPEP §2144.03, for the elements and properties of smart cards to be combined with Keene that make the invention of claim 3 obvious and for the alleged motivation to combine.

With respect to claim 4, the Office Action states that Keene discloses that a PIN is used to extract private information. Further, the Office Action takes official notice that a user ID can be private and states that it would have been "obvious for one of ordinary skill in the art to make the patient enter his PIN to access information in the card, for increased security and privacy". Applicant requests that the Patent Office cite to an authority, pursuant to MPEP §2144.03, for the elements and properties of smart cards and/or PIN usage to be combined with Keene that make the invention of claim 4 obvious and for the alleged motivation to combine.

In addition, Applicant asserts that the Office Action has failed to establish a *prima facie*

case that claims 3 and 4 are obvious over Keene in light of alleged knowledge in the art at the time of filing, even without cited authorities to support the official notice of the various allegedly known facts to be combined with Keene. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, the prior art reference, or combination of references, must teach or suggest all the limitations of the claims. *In re Wilson* 424 F.2d 1382, 1385 (CCPA 1970). Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. See *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Lastly, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991). Further, the teachings or suggestions, as well as the expectation of success, must come from the prior art, not applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

To establish a *prima facie* case of obviousness, the combination of Keene and the official notice of facts concerning smart cards and PIN usage must teach or suggest all the limitations of the claims. Applicant asserts that the combination cited in the Office Action fails to teach or suggest all the limitations of claims 3 and 4.

Claims 3 and 4 depend from claim 1, a method directed to ensuring the security of a patient's data from a medical test conducted by a laboratory. Claim 3 states that the patient's medical data card includes a memory, and that the method of claim 1 further comprises storing the test results in the memory on the patient's medical data card. Claim 4 recites that the patient identification number is not readable from the patient's medical data card without a PIN, and that generating the first medical test request step of claim 1 includes the patient supplying the PIN.

As noted above in the argument as to why Keene does not anticipate claim 1, Keene does not teach or suggest transmitting a patient specimen and a first medical test request to a secure data provider and does not teach or suggest a secure data provider that performs the functions recited in claim 1. A *prima facie obviousness* rejection of claim 3 over Keene in view of the official notice that smart cards are used to store patient medical information requires that the combination cited provide these elements that are missing in Keene. The Office Action stated "it would have been obvious to implement Keene's method on such a card so as to eliminate the need for the patient to carry multiple cards." Even if the combination of references cited in the Office Action provides the knowledge and motivation to implement *Keene's* method using a smart card storing the test

results in its memory, the resulting method does not include (a) transmitting a patient specimen and a first medical test request to a secure data provider or (b) a secure data provider that performs the functions recited in claim 1. Consequently, as the cited combination in the Office Action fails to teach or suggest all the limitations of claim 3, the Office Action fails to establish a *prima facie* case that claim 3 is obvious over Keene in light of alleged knowledge in the art at the time of filing.

Similarly, with respect to the rejection of claim 4 by the Office Action, Applicant noted above that the method disclosed by Keene failed to anticipate claim 1 because it lacked the step of transmitting a patient specimen and a first medical test request to a secure data provider and because Keene does not disclose a secure data provider that performs the functions recited in claim 1. Therefore, to establish a *prima facie* case of obviousness to reject the method of dependent claim 4 over Keene in view of the official notice that a user ID can be private, the cited combination must provide the elements that are missing in Keene.

The Office Action states that it "would have been obvious for on[e] of ordinary skill in the art to make the patient enter his PIN to access information in the card, for increased security and privacy. Even if the combination cited in the Office Action provides the knowledge and motivation to implement *Keene's* method with a private user ID, the resulting method does not include (a) transmitting a patient specimen and a first medical test request to a secure data provider or (b) a secure data provider that performs the functions recited in claim 1. Thus, as the cited combination in the Office Action fails to teach or suggest all the limitations of claim 4, the Office Action fails to establish a *prima facie* case that claim 4 is obvious over Keene in light of alleged knowledge in the art at the time of filing.

As a *prima facie* case of obviousness has not been established against either claim 3 or claim 4, Applicant requests withdrawal of the 35 USC §103(a) rejections of these claims.

The Office Action takes official notice with respect to claim 7 that smart cards are used to store patient medical information and that it would have been obvious for one of ordinary skill in the art to implement Keene's method on such a card, so as to eliminate the need for the patient to carry multiple cards. Applicant requests that the Patent Office cite an authority, pursuant to MPEP §2144.03, for the elements and properties of smart cards to be combined with Keene that make the invention of claim 7 obvious and for the alleged motivation to combine.

In addition, Applicant asserts that the Office Action has failed to establish a *prima facie* case that claim 7 is obvious over Keene in light of alleged knowledge in the art at the time of filing, even without cited authorities to support the official notice of the various allegedly known facts

about the elements and properties of smart cards to be combined with Keene. As noted above, to establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. In particular, the prior art reference, or combination of references, must teach or suggest all the limitations of the claims. *In re Wilson* 424 F.2d 1382, 1385 (CCPA 1970).

Applicant asserts that the combination cited in the Office Action fails to teach or suggest all the limitations of claim 7. Claim 7 depends from claim 6, which is directed to a method of ensuring the security of patient's data from medical tests conducted for a medical provider by a laboratory. As noted above in the argument as to why Keene does not anticipate claim 6, several of the elements of claim 6 are not disclosed in Keene. In particular, Keene does not disclose a method in which the test results, in *any form*, are provided to the medical provider, as required in the final step of claim 6. The method of Keene also does not disclose a step of receiving from the medical provider a first medical test request generated using the patient's medical data card and a patient specimen for use in conducting the test. Further the method disclosed by Keene does not include steps of generating a second medical test request using the first medical test request, the second medical test request being devoid of publicly accessible information about the identity of the patient or of forwarding a second medical test request and a patient specimen to a *laboratory* for conducting the test.

To establish a *prima facie* obviousness rejection of claim 7 over Keene in view of the official notice that smart cards are used to store patient medical information requires that the combination cited, of Keene and the official notice, provide the steps of the method of claim 6 that are missing in Keene. The Office Action states "it would have been obvious to implement Keene's method on such a card so as to eliminate the need for the patient to carry multiple cards." However, even if the combination of references cited in the Office Action provides the knowledge and motivation to implement *Keene's* method using a smart card storing the test results in its memory, the resulting method does not include these steps of amended claim 6 that are missing in Keene. The cited combination in the Office Action fails to teach or suggest all the limitations of claim 6 and therefore fails to teach or suggest all the limitations of claim 7. Thus, the Office Action fails to establish a *prima facie* case that claim 7 is obvious over Keene in light of alleged knowledge in the art of smart cards at the time of filing.

In view of the above, Applicant requests reconsideration and withdrawal of the rejection of claim 7 under 35 USC §103(a).

The Office Action rejects claims 10-17 under 35 USC §103(a) as being unpatentable over

Keene. The Office Action takes official notice that smart cards can store a variety of information, the information is often encrypted, and stored in a barcode or magnetic strip. The Office Action states that the test request card of claims 10-12 and the test results card of claims 13-17 would therefore have been obvious for one of ordinary skill in the art, with the motivation of security and mobility. Applicant requests that the patent office cite an authority, pursuant to MPEP §2144.03, for the properties of smart cards to be combined with Keene that make the inventions of claims 10-12 and 13-17 obvious and for the alleged motivations to combine of security and mobility.

In addition, Applicant asserts that the Office Action has failed to establish a *prima facie* case that claims 10-12 and 13-17 are obvious over Keene in light of alleged knowledge in the art at the time of filing, even without cited authorities to support the official notice of the various allegedly known facts to be combined with Keene. As noted above, to establish a *prima facie* case of obviousness, the combination of Keene and the official notice of facts concerning smart cards must teach or suggest all the limitations of the claims 10-12 and 13-17 and must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine the references.

Claims 10-12 are directed to a test request card for use in a system for ensuring the security of a patient's data from a medical test conducted for a medical provider by a laboratory. The test request card includes encrypted information identifying the patient, the medical test requested, an identification of the medical provider, a unique patient identification number, and a public encryption public code.

Claims 13-17 are directed to a test results card for use in a system for ensuring the security of a patient's data from a medical test conducted for a medical provider by a laboratory. The test results card includes encrypted information identifying the patient and results of the medical test.

Applicant asserts that while Keene discloses a member identification card, there is no disclosure, explicit or implicit, of either a test request card with the elements of claims 10-12 or a test results card with the elements of claims 13-17. In addition, Keene appears actively to teach away from the motivation stated in the Office Action as Keene discloses achieving security of a patient's medical test results by informing the patient directly of the results and, if the patient permits, by storing the medical test results in a database accessible by telephone only with the appropriate account number and PIN (col 3, line 61 to col 4, line 6).

Thus, in the absence of a cited authority for the official notice of the elements of smart cards to be combined with Keene and with a lack of a motivation to combine Keene with the use of

a smart card, Applicant asserts that the Office Action fails to establish a *prima facie* case that claims 10-12 and 13-17 are obvious over the cited prior art.

In view of the above, Applicant requests reconsideration and withdrawal of the rejections of claims 10-17 under 35 USC §103(a).

In view of the amendments to the claims and the remarks above, Applicant believes the claims are in condition for allowance and respectfully requests such favorable action.

Should any questions arise, or if Applicant or Applicant's Agent can facilitate further examination of this application, please contact the undersigned Agent so that any remaining issues can be resolved.

Respectfully submitted,

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REPLACEMENT PAGE

METHODS AND APPARATUS FOR ENSURING THE PRIVACY AND SECURITY OF PERSONAL MEDICAL INFORMATION

FIELD OF THE INVENTION

This invention relates to methods and devices for ensuring the privacy and security of personal medical information, and in particular to methods and devices for ensuring the privacy and security of personal genetic information.

BACKGROUND OF THE INVENTION

As knowledge of the human genome increases, an increasing number of genetic markers are being identified as either the cause of, or being associated with, an increased risk of developing various diseases and conditions. Genetic testing for these markers will allow physicians to identify those at risk of developing certain diseases and take action to prevent, or at least reduce the risk of developing, these diseases. It is also possible to test for genetic markers associated with variations in drug response, and to predict how a patient will respond to a particular drug treatment. However, despite the obvious medical benefit, people may be hesitant to permit such testing for fear that they might be discriminated against by prospective employers and insurers due to an increased risk of disease revealed by such a test, or an indication that a patient is not responsive to conventional treatment revealed by such a test. Thus, ensuring the privacy and security of medical information, and particularly genetic testing information, is important to encourage the public to permit such testing.

Some efforts have been made to provide anonymity for medical test results. For example, in the past numbered test kits have been available with which a person can take a sample, such as a blood sample, and mail the sample to the issuing laboratory, and anonymously call in for the test results by referencing the number on the test kit. However in many instances such a patient-initiated testing system is not appropriate, for example where it is not apparent to the patient what type of test to order, where the collection of the sample is not routine or within the ability of the patient, or where the significance of, or interpretation of, the results is not within the ability of patient. This is particularly true for testing for efficacy of certain courses of drug therapy. In these instances, a patient needs the assistance of a health care professional, and may avoid valuable tests out of concern for the privacy and security of the test results.

SUMMARY OF THE INVENTION

Generally, the method of this invention allows for the private and secure reporting of a patient's medical tests. The method comprises providing the patient with a medical data

REPLACEMENT PAGE

METHODS AND APPARATUS FOR ENSURING THE PRIVACY AND SECURITY OF PERSONAL MEDICAL INFORMATION

ABSTRACT OF THE DISCLOSURE

A method of ensuring the security of data from a medical test includes providing the patient with a medical data card issued by a secure information provider, and having a unique patient identification number (PID), a public key encryption private key, and a public key encryption public key (Key 2). The method further includes a first test request card having an encrypted identification of the patient and the test, a health care provider code, Key 2, and the test type that accompanies the patient's test specimen to the secure information provider; a second test request card bearing an encryption of the PID and the test type to forward with the patient's specimen to a testing laboratory; a first test results card bearing an encryption of the PID and the results; and a second test results card that may be read in conjunction with the patient's medical data card.